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TRANSMITTAL FORM

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Application Number	10/680,742
Filing Date	10/06/2003
First Named Inventor	James E. Hagstrom, et al.
Group Art Unit	
Examiner Name	
Total Number of Pages in This Submission: 157	Attorney Docket Number: 13.3.8

ENCLOSURES *(check all that apply)*

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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual name	Mirus Corporation
Signature	
Date	08/02/2004

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: 08/02/2004

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Signature		Date	08/02/2004

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OIPE JC41 AUG 07 2004 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **James E. Hagstrom, Mark Noble, Julia Hegge, Vladimir G. Budker**)

Serial No.: **10/680,742**)

Filed: **10/06/2003**)

Group Art Unit:)

For: **Processes for Delivery of Polynucleotides to the Prostate**

INFORMATIONAL STATEMENT

Commissioner of Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449. This information statement supplements the previously filed information statement.

US patent

5,698,531	Nabel et al.	12/6/97
5,521,291	Curiel,.David T	05/28/96
5,580,859	Felgner, Philip L.	12/03/96
5,583,020	Sullivan, Sean	12/1/96
5,922,687	Mann, Micheal	07/13/99

International Patent

PCT/US98/27072		07/01/99

REFERENCES CITED

Acsadi G et al. "Direct gene transfer and expression into rat heart in vivo." The New Biologist 1991 Vol. 3 no. 1 pp. 71-81

Barron LG et al., "Cationic Lipids Are Essential For Gene Delivery Mediated By Intravenous Administration of Lipoplexes." Gene Therapy 1999 Vol. 6 pp.1179-1183.

Bohm W et al., "Routes of Plasmid DNA Vaccination That Prime Murine Humoral and Cellular Immune Responses." Vaccine 1998; Vol. 16, No. 9/10; pp. 949-954.

Budker V et al., "Naked DNA Delivered Intraportally Expresses Efficiently in Hepatocytes." Gene Therapy 1996; Vol. 3 pp. 593-598.

Budker V et al., "The Efficient Expression of Intravascularly Delivered DNA in Rat Muscle." Gene Therapy 1998 Vol. 5 pp. 272-276.

Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," Circ. Res; 1992 Vol. 71 pp. 27-33

Coll JL et al. "In Vivo Delivery to Tumors of DNA Complexed With Linear Polyethylenimine." Human Gene Therapy 1999 Vol. 10 pp. 1659-1666.

Goula, D. Et al., "Polyethylenimine-Based Intravenous Delivery of Transgenes to Mouse Lung." Gene Therapy 1998/5; pp.1291-1295.

Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." Nature; 1999 Vol. 5 no. 4 pp. 439-443

Hengge UR et al. "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," Nature Genetics; 1995 Vol. 10 pp. 161-166

Hickman MA et al. "Gene expression following direct injection of DNA into liver," Hum Gene Ther; 1994 Vol. 5, no. 12 pp. 1477-1483

Kawabata, K. Et al., "The Fate of Plasmid DNA After Intravenous Injection in Mice: Involvement of Scavenger Receptors in Its Hepatic Uptake." Pharmaceutical Research 1995; Vol. 12, No. 6; pp. 825-830.

Liu F et al. "Hydrodynamics-based transfection in animals by systemic administration of plasmid DNA," Gene Ther; 1999 Vol. 6 pp. 1258-1266

Liu Y et al. "Cationic Liposome-Mediated Intravenous Gene Delivery." J Biol Chem 1995 Vol. 270 No. 42; pp. 24864-24870.

Malone RW et al. "Dexamethasone enhancement of gene expression after direct hepatic DNA injection," J Biol Chem; 1994 Vol. 269, no. 47 pp. 29903-29907

McLean JW et al., "Organ-Specific Endothelial Cell Uptake of Cationic Liposome-DNA Complexes in Mice." The American Physiological Society 1997; pp. H387-H404.

Meyer KB et al. "Intratracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," Gene Ther; 1995 Vol. 2, no. 7 pp. 450-460

Milas M et al. "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," Clin Cancer Res; 1997 Vol. 3 no. 12 Pt. 1, pp. 2197-203

Riessen R et al. "Arterial gene transfer using pure DNA applied directly to a hydrogel-coated angioplasty balloon," Hum Gene Ther; 1993 Vol. 4, no. 6 pp. 749-758

Sikes ML et al. "In vivo gene transfer into rabbit thyroid follicular cells by direct DNA injection," Hum Gene Ther; 1994 Vol. 5, no. 7 pp. 837-844

Song YK et al., "Enhanced Gene Expression in Mouse Lung by Prolonging the Retention Time of Intravenously Injected Plasmid DNA." Gene Therapy 1998; 5; pp. 1531-1537.

Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," PNAS; 1983 Vol. 80 pp. 7128-7131

Vile RG et al. "In vitro and in vivo targeting of gene expression to melanoma cells," Cancer Res; 1993 Vol. 53 pp. 962-967

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Wolff JA et al. "Direct gene transfer into mouse muscle in vivo." Science 1990 Vol 247 pp. 1465-1468.

Zhang et al. "Efficient expression of naked dna delivered intraarterially to limb muscles of nonhuman primates," Human Gene Therapy 2001 Vol. 12 no. 4 pp. 427-438

Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA," Human Gene Therapy 1999; Vol. 10 pp. 1735-1737

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Zhu N et al., "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice." Science 1993; Vol. 261 pp. 209-211.

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

Respectfully submitted,

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(414) 821-5690

I hereby certify that this correspondence is being sent by United States Postal Service mail to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on: ~~November 6, 2003.~~ 8-2-04

Kirk Ekena

INFORMATION DISCLOSURE STATEMENT BY APPLICANT FORM PTO-1449	Attorney Docket No.: **Mirus.013.03.8**	Serial No.: **10/680,742**
	Applicant: **James E. Hagstrom, Mark Noble, Julia Hegge, Vladimir Budker**	Group:
		Examiner:

OIPE
AUG 07 2004
PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

Examiner Intl	Seq	Patent Number	Issue Date	Patentee	Class	Sub Class	Filing Date
		5,698,531	12/6/97	Nabel et al.			
		5,521,291	05/28/96	Curiel, David T			
		5,580,859	12/03/96	Felgner, Philip L.			
		5,583,020	12/1/96	Sullivan, Sean			
		5,922,687	07/13/99	Mann, Micheal			

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		Document Number	Publication Date	Country or Patent Office	Class	Sub Class	Transl. yes	Transl. no
		PCT/US98/27072	07/01/99					

OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

		Acsadi G et al. "Direct gene transfer and expression into rat heart in vivo." The New Biologist 1991 Vol. 3 no. 1 pp. 71-81
		Barron LG et al., "Cationic Lipids Are Essential For Gene Delivery Mediated By Intravenous Administration of Lipoplexes." Gene Therapy 1999 Vol. 6 pp.1179-1183.
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		McLean JW et al., "Organ-Specific Endothelial Cell Uptake of Cationic Liposome-

		DNA Complexes in Mice." The American Physiological Society 1997; pp. H387-H404.
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		Zhu N et al., "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice." Science 1993; Vol. 261 pp. 209-211.

Examiner:	Date Considered: